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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Otto E. Anderhub

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,668	Applicant(s) ANDERHUB ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-27,31-50,52-65 and 87-103 is/are pending in the application.
- 4a) Of the above claim(s) 91-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-27,31-50,52-65,87-90 and 95-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>WO 02/39810</u> |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 6 May 2009.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Submitted claim 91-94 are directed to an embodiment that is distinct from the embodiment originally claimed for the following reasons: Independent claims 1, 26, 50 recite that the cutter is engaged with a recess on the holder and the storage portion is engaged with a recess on the holder. Claims 91-94 recite that the cutting portion is engaged via a recess and protrusion with the storage portion.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 91-94 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 and 58 recite the limitation "the end effector portion". There is insufficient antecedent basis for this limitation in the claim. For the purpose of examination, the Examiner will assume that Claims 57 and 58 are referring to the end effector portion in Claim 56.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1, 2, 6-12, 14, 15, 17-27, 31-39, 41-44, 95-96 is rejected under 35 U.S.C. 103(a) as being obvious over Cohen et al. (US Patent Application 2005/0054945) in view of Krzyzanowski (US Patent 6,440,085).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

Art Unit: 3734

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Claim 1, 2, 6, 14, 15, 18, 19, 20, 21, 22, 23, 24, 25, 95: Cohen'945 teaches a first jaw (30), a jaw assembly that contains a cutting portion (55), a holder (50), and a storage portion (16). There is a groove (60) on the holder for receiving a protrusion (70) on the storage portion (paragraph [0048], [0049]). Cohen'945 does not teach that the cutter is separable from the holder.

Krzyzanowski'085 teaches a forceps that contains a holder (26) configured to receive a cutting portion (27). The holder contains a groove for receiving a protrusion on the cutter (the groove is unlabeled but can best be seen in Figure 7 in light of Figures 3 and 4). In light of this, the claim would be obvious because the known technique of attaching a removable cutting blade to a forceps jaw with a protrusion fitting into a groove was recognized as part of the ordinary capabilities in the art.

Claims 7, 8, 9, 10, 11: Cohen'945 in view of Krzyzanowski'085 discloses or makes obvious the invention as claimed with the exception the materials of the different components.

Regarding the material of the different components, the examiner contends that this is nothing more than an obvious design choice. Cutting edges were previously known as being manufactured out of plastic or metal. Forming two removable components out of different materials would allow for one material to be sharpened and the other material to be less expensive, for example.

Claim 12, 17: Cohen'945 teaches that the first jaw (30) contains a holder and a cutting portion (37).

Claim 26, 27, 37, 38 39, 41, 42, 43, 44, 96: Cohen'945 teaches a proximal handle (9) coupled to a distal end effector assembly (see Figure 1) via an elongate member (12). The end effector assembly contains a first jaw (30) and a jaw assembly having a cutting portion (55), a holder (50), a storage portion (16). There is a groove (60) on the holder for receiving a protrusion (70) on the storage portion (paragraph [0048], [0049]). Cohen'945 does not teach that the cutter is separable from the holder.

Krzyzanowski'085 teaches a forceps that contains a holder (26) configured to receive a cutting portion (27). The holder contains a groove for receiving a protrusion on the cutter (the groove is unlabeled but can best be seen in Figure 7 in light of Figures 3 and 4). In light of this, the claim would be obvious because the known technique of attaching a removable cutting blade to a forceps jaw with a protrusion fitting into a groove was recognized as part of the ordinary capabilities in the art.

Claims 31, 32, 33, 34, 35: Cohen'945 in view of Krzyzanowski'085 discloses or makes obvious the invention as claimed with the exception the materials of the different components.

Regarding the material of the different components, the examiner contends that this is nothing more than an obvious design choice. Cutting edges were previously known as being manufactured out of plastic or metal. Forming two removable components out of different materials would allow for one material to be sharpened and the other material to be less expensive, for example.

Claim 36: Cohen'945 teaches that the first jaw (30) contains a holder and a cutting portion (37).

Claim 16, 40, 87 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen'945 in view of Krzyanowski'085, as applied to Claim 1 and 26, further in view of Slater et al. (US Patent 5,482,054).

Claims 16, 40: Cohen'945 in view of Krzyanowski'085 teach the limitations of Claim 16 and 26 except for a non-straight portion connecting a tang to a cutting edge.

Slater'054 shows that it is known to connect a cutter (418; Figure 8b) with a non-straight portion (portion of 418 between 30 and cutting element 20 in Figure 8b) to a tang (proximal end of element 418 surrounding openings 66 and 419) to a cutting edge (20) that is configured to be received in a gap in the holder (Figures 8a-8c). The claim would have been obvious because the known technique using a tang and non-straight connector portion to place a cutting element in a jaw was recognized as part of the ordinary capabilities of one skilled in the art.

Claims 87, 88: The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66).

Claims 50, 52-65, 90, 97-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen'945 in view of Krzyzanowski'085 in view of Slater'054.

Claim 50, 52, 59, 60, 61, 62, 63, 64, 65, 89, 99, 102, 103: Cohen'945 teaches a proximal handle (9) coupled to a distal end effector assembly (see Figure 1) via an elongate member (12). The end effector assembly contains a first jaw (30) and second end effector assembly having a cutting portion (55), a holder (50), a storage portion (16). There is a groove (60) on the holder for receiving a protrusion (70) on the storage portion (paragraph [0048], [0049]). Cohen'945 does not teach that the cutter is separable from the holder.

Krzyzanowski'085 teaches a forceps that contains a holder (26) configured to receive a cutting portion (27). The holder contains a groove for receiving a protrusion on the cutter (the groove is unlabeled but can best be seen in Figure 7 in light of Figures 3 and 4). In light of this, the claim would be obvious because the known technique of attaching a removable cutting blade to a forceps jaw with a protrusion fitting into a groove was recognized as part of the ordinary capabilities in the art.

Cohen'945 in view of Krzyzanowski'085 do not teach a non-straight portion connecting a tang to a cutting edge.

Slater'054 shows that it is known to connect a cutter (418; Figure 8b) with a non-straight portion (portion of 418 between 30 and cutting element 20 in Figure 8b) to a tang (proximal end of element 418 surrounding openings 66 and 419) to a cutting edge (20) that is configured to be received in a gap in the holder (Figures 8a-8c). The claim would have been obvious because the known technique using a tang and non-straight

Art Unit: 3734

connector portion to place a cutting element in a jaw was recognized as part of the ordinary capabilities of one skilled in the art.

Claim 53, 54, 55: Cohen'945 in view of Krzyzanowski'085 discloses or makes obvious the invention as claimed with the exception the materials of the different components.

Regarding the material of the different components, the examiner contends that this is nothing more than an obvious design choice. Cutting edges were previously known as being manufactured out of plastic or metal. Forming two removable components out of different materials would allow for one material to be sharpened and the other material to be less expensive, for example.

Claim 56, 57, 58: Cohen'945 teaches that the first jaw contains a holder (30) and an end effector (37) portion. These parts are formed separately.

Claim 90: The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66).

Claim 97, 98: The non-straight portion of Slater'054 is a substantially vertical wall that is substantially orthogonal to a plane of a sample hole on the second end effector.

Claim 99: Slater'054 shows that the holder (518) has a bridging portion (region between bore 30 on the holder 518). In light of the rejection to Claim 50 above, it would be obvious to use a similar connection structure to attach the holder to the cutter.

Claim 100, 101: The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66). Slater'054 further shows that the bores/holes are aligned (Figure 8a).

Art Unit: 3734

Claim 1, 2, 6-11, 13-15, 17-27, 31-35, 37-39, 42-46, 48, 95, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krzyzanowski (US Patent 6,440,085) in view of Caisley (WO 02/39810).

Claims 1, 2, 6, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 37, 38, 39, 42, 43, 44, 45, 46, 48, 95, 96, : Krzyzanowski'085 teaches a biopsy device with an end effector that contain a first jaw (30) and a jaw assembly having a holder (26) pivotally connected to the first jaw having a cutting portion (27). The holder contains a groove for receiving a protrusion on the cutter (the groove is unlabeled but can best be seen in Figure 7 in light of Figures 3 and 4). Krzyzanowski'085 teaches that the jaw is configured to store a sample because of its intended use and cup-shape. Krzyzanowski'085 further teaches actuating wires (24) extending through an elongate member (12).

Krzyzanowski'085 does not teach a removable storage portion having a protrusion that is received by a groove on the holder.

Caisley'801 teaches a sample collection container (1) that is attached to a holder (Figure 3) with a protrusion (shown clearly, but labeled in Figure 1b) that engages a groove (17; page 9, line 11 to page 10, line 20) on the holder base in order to create a removable storage container for the sample. It would be obvious to one of ordinary skill in the art to modify the device of Krzyzanowski'085 with a removable sample container, as taught by Caisley'801 in order to provide an easy way to capture the entire sample after it is taken from the patient.

Claims 7, 8, 9, 10, 11, 31, 32, 33, 34, 35: Krzyzanowski'085 in view of Caisley'801 discloses or makes obvious the invention as claimed with the exception the materials of the different components.

Regarding the material of the different components, the examiner contends that this is nothing more than an obvious design choice. Cutting edges were previously known as being manufactured out of plastic or metal. Forming two removable components out of different materials would allow for one material to be sharpened and the other material to be less expensive, for example.

Claims 1, 16, 26, 40, 50, 52-62, 64, 90 and 97-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krzyzanowski'085 in view of Caisley'801 in view of Slater et al. (US Patent 5,482,054).

Claim 1, 16, 26, 40, 50, 52, 56, 57, 58, 59, 60, 61, 62, 64, 102, 103:
Krzyzanowski'085 teaches a biopsy device with an end effector that contain a first jaw (30) and a jaw assembly having a holder (26) pivotally connected to the first jaw having a cutting portion (27). The holder contains a groove for receiving a protrusion on the cutter (the groove is unlabeled but can best be seen in Figure 7 in light of Figures 3 and 4). Krzyzanowski'085 teaches that the jaw is configured to store a sample because of its intended use and cup-shape.

Krzyzanowski'085 does not teach a removable storage portion having a protrusion that is received by a groove on the holder.

Caisley'801 teaches a sample collection container (1) that is attached to a holder (Figure 3) with a protrusion (shown clearly, but labeled in Figure 1b) that engages a

Art Unit: 3734

groove (17; page 9, line 11 to page 10, line 20) on the holder base in order to create a removable storage container for the sample. It would be obvious to one of ordinary skill in the art to modify the device of Krzyzanowski'085 with a removable sample container, as taught by Caisley'801 in order to provide an easy way to capture the entire sample after it is taken from the patient.

Krzyzanowski'085 in view of Caisley'801 do not teach a non-straight portion connecting a tang to a cutting edge.

Slater'054 shows that it is known to connect a cutter (418; Figure 8b) with a non-straight portion (portion of 418 between 30 and cutting element 20 in Figure 8b) to a tang (proximal end of element 418 surrounding openings 66 and 419) to a cutting edge (20) that is configured to be received in a gap in the holder (Figures 8a-8c). The claim would have been obvious because the known technique using a tang and non-straight connector portion to place a cutting element in a jaw was recognized as part of the ordinary capabilities of one skilled in the art.

Claim 53, 54, 55: Cohen'945 in view of Krzyzanowski'085 discloses or makes obvious the invention as claimed with the exception the materials of the different components.

Regarding the material of the different components, the examiner contends that this is nothing more than an obvious design choice. Cutting edges were previously known as being manufactured out of plastic or metal. Forming two removable components out of different materials would allow for one material to be sharpened and the other material to be less expensive, for example.

Claim 90: The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66).

Claim 97, 98: The non-straight portion of Slater'054 is a substantially vertical wall that is substantially orthogonal to a plane of a sample hole on the second end effector.

Claim 99: Slater'054 shows that the holder (518) has a bridging portion (region between bore 30 on the holder 518). In light of the rejection to Claim 50 above, it would be obvious to use a similar connection structure to attach the holder to the cutter.

Claim 100, 101: The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66). Slater'054 further shows that the bores/holes are aligned (Figure 8a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 3734

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/L. B./

Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734